AOS

ADVANCED ORTHOPAEDIC SOLUTIONS

K070444

JUN 14 2007

510(k) SUMMARY

SUBBMITTED BY:	Advanced Orthopaedic Solutions 2444 205TH Street, Unit 5 Torrance, CA, 90501 (310) 533-9966 FAX (310) 533-9876
510(k) CONTACT PERSON:	Paul Doner, Vice President Operations
TRADE NAME:	AOS Tibial Nail
COMMON NAME:	Intramedullary Fixation Rod
CLASSIFICATION:	21 CFR 888.3020 Intramedullary Fixation Rod
DEVICE CODE:	HSB
SUBSTANTIALLY EQUIVALENT DEVICE:	DePuy VersaNail Tibial Nail (K032097) Smith & Nephew TriGen Meta-Nail Tibial Nail System (K061019) Stryker Trauma T2 Tibial Nail System

DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:

The AOS Tibial Nail is an intramedullary fixation device for the temporary fixation of fractures of the tibia and is intended as a load sharing device which may be removed once the fracture has healed.

The AOS Tibial Nail is a titanium intramedullary nail system consisting of an intramedullary nail, proximal and distal locking screws and end caps.

The Tibial Nail is a cannulated nail with a 10° proximal bend and a 3° distal bend. The proximal diameter of the nail is 11.5mm and it is produced in 8mm, 9mm, 10mm and 11mm distal diameters. The proximal end of the nail has two holes to accept the 5.0 mm cortical screw and one slot which also accept the 5.0mm cortical screw. The proximal end of the nail is threaded to accept an end cap.

The distal end of the nail contains three cross locking holes which accept a 5.0mm cortical screw for diameter of 9mm, 10mm and 11mm and a 4.2mm screw for the 8mm diameter nail.

SUBSTANTIAL EQUIVALENCE INFORMATION:

The principals of operation of this device are similar to that of the predicate device. There are no chances in the intended use, and the operating principles, performance specification and materials of composition are similar to that of the predicate device. Mechanical testing has shown that the AOS Tibial Nail is substantially equivalent to the predicate device.

INTENDED USE:

The AOS Tibial Nail System is intended to provide temporary stabilization of various types of fractures, malunions and nonunion of the tibia. The AOS Tibial Nail System is indicated for long bone fracture fixation of tibial fractures, which may include the following: transverse, oblique, spiral, segmental and comminuted fractures; fractures with bone loss and bone transport; open and closed fractures, pathologic fractures; corrective osteotomies; pseudarthrosis of the tibial shaft; nonunions, malunions, metaphyseal and epiphyseal fractures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Advanced Orthopaedic Solutions, Inc.
c/o Mr. Paul Doner
Vice President Operation
2444 205th Street, Unit 5
Torrance, California 90501

Re: K070444
Trade/Device Name: AOS Tibial Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: May 17, 2007
Received: May 18, 2007

JUN 14 2007

Dear Mr. Doner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or on the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indication for Use Statement

510(k) Number (if known): K070444

Device Name: AOS Tibial Nail

Indications for Use:

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The AOS Tibial Nail System is indicated for long bone fracture fixation of tibial fractures, which may include the following:

- Transverse, oblique, spiral, segmental and comminuted fractures;
- Fractures with bone loss and bone transport;
- Open and closed fractures, pathologic fractures;
- Corrective osteotomies; pseudarthrosis of the tibial shaft;
- Nonunions, malunions, metaphyseal and epiphyseal fractures.

Prescription Use: X AND/OR Over-The-Counter Use: ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070444